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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,045	03/16/2001	Robert E. Scott	D6386/D	7993

7590

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/25/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,045

Applicant(s)

SCOTT, ROBERT E.

Examiner

Misook Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 10-12 are pending and examined on merits.

Specification

The disclosure is objected to because of the following informalities: This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. 37 CFR 1.821(a) presents a definition for "nucleotide and/or amino acid sequences." The instant application contains an unbranched specifically defined sequence of more than ten nucleotides at pages 12, 13 and 15. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Branched sequences are specifically excluded from this definition. Sequences with fewer than four specifically defined nucleotides or amino acids are specifically excluded from this section. "Specifically defined" means those amino acids other than "Xaa" and those nucleotide bases other than "n" defined in accordance with the World Intellectual Property Organization (WIPO) Handbook on Industrial Property Information and Documentation, Standard ST.25: Standard for the Presentation of Nucleotide and Amino Acid Sequence Listings in Patent Applications (1998), including Tables 1 through 6 in Appendix 2 (see MPEP § 2422). SEQ ID NOs are required for the sequences in Figures 2 and 6, at page 24 lines 4-6.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10 and 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is confusing because it recites "P2P cDNA". Does the P2P cDNA mean SEQ ID NO:2? The Figure 1, 2, 6 legends at page 7 and 10 seem to indicate P2P cDNA is a specific cDNA encoding the protein shown in Figure 1. However, the art recognizes the terminology "P2P" as a large group of proteins with molecular weight of 30-40 kD that are associated with the 30-40S substructures of nuclear heterogenous ribonuclear proteins. See abstract of Minoo et al (Nov. 1989, The Journal of Cell Biology, Vol. 109, pages 1937-1946 and the specification at page 2 lines 3-11, especially lines 6-8 says that P2P is not just the protein shown in Figure 2 encoded by the cDNA shown in Figure 6 but plural proteins recognized by the art.

For the purpose of this office action, this examiner will assume that protein products of P2P cDNA are plural P2P proteins (defined at page 2 lines 6-8 of the specification) encoded by plural P2P cDNA.

However, this treatment does not relieve applicant the burden of responding to this rejection.

Claim 11 is confusing because it recites "carboxy-terminal half of the polypeptide shown in Figure 2." SED ID NO to the corresponding "carboxy-terminal half of the polypeptide shown in Figure 2" will obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

Claim 12 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one

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skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 12 recite an antibody produced by specific hybridoma cell lines.

It is apparent that the recited cell lines are required to practice the claimed invention, because they are specifically required in the claims. As required elements they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the cell lines listed in claim 7. See 37 CFR 1.802.

The specification does not provide a repeatable method for obtaining the cell lines of claim 7, and they do not appear to be readily available material. Deposit of the cell lines would satisfy the enablement requirements of 35 U.S.C. 112. While the specification states on page 5 that the cell lines "have been deposited for patent purposes", the specification does not indicate the terms of the deposit.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

If a deposit is not made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made at an acceptable depository and that the following criteria have been met:

(a) during the pendency of this application, access to the invention will be afforded to one determined by the Commissioner to be entitled thereto;

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(b) all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained for a term of at least thirty (30) years and at least five (5) years after the most recent request for the furnishing of a sample of the deposited material;

(d) a viability statement in accordance with the provisions of 37 CFR 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition the identifying information set forth in 37 CFR 1.809(d) should be added to the specification. See 37 CFR 1.803 - 37 CFR 1.809 for additional explanation of these requirements.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claim 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by either Minoo et al (Nov. 1989, The Journal of Cell Biology, Vol. 109, pages 1937-1946) or Witte et al (1993, Mol. Cell. Differ. Vol 2, pages 185-195).

Claim 10 is drawn to an isolated antibody that binds to P2P (proliferation potential proteins) described at page 2 lines 3-11 of the instant specification and claim 11 is drawn to an antibody to the specific protein in Figure 2. Minoo et al (Nov. 1989, The Journal of Cell Biology, Vol. 109, pages 1937-1946) teach, at Figures 1-8 and at page 1938 left column the second last paragraph from bottom, antibodies, i.e. iD2 and fA12 and AC88 that bind to P2P protein products. The specification at page 17 lines 12-23 says cloning of the cDNA encoding the protein shown in Figure 2 was possible because the two antibodies, i.e., AC88 and fA12 taught by Minoo et al (cited above) bind to the protein produced by the clone A and clone B which are two halves of the cDNA shown in Figure 6. Witte et al also teach antibody that binds to P2P and this antibody AC88 binds to the protein in Figure 2 according to the specification at page 17 lines 12-23.

Thus, either Minoo et al or Witte et al teach antibodies that binds to P2P protein or C-terminal half of the polypeptide shown in Figure 2.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that antibody of the prior art do not bind to the C-terminal half of the protein in Figure 2. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claims 10 and 11 rejected under 35 U.S.C. 102(e) as being anticipated by US PAT 5,634,761.

Claim 10 is drawn to an isolated antibody that binds to P2P (proliferation potential proteins) described at page 2 lines 3-11 of the instant specification and claim 11 is drawn to an antibody that binds the protein in Figure 2.

US PAT 5,634,761 teaches in Figure 14 and column 4 lines 44-51 antibody binds to P2P.

The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that antibody of the prior art do not bind to the C-

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terminal half of the protein in Figure 2. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibody is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Misook Yu, Ph.D.
September 8, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600